CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-452

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS REVIEW

NDA:	20-452/S-000
Submission Date:	December 19, 2002
Drug Name:	PARAPLATIN® — (Carboplatin)
Dosage Form:	50 mg, 150 mg, and 450 mg Single-Dose Vials for Intravenous Injection
Sponsor:	Bristol-Myers Squibb Company
Reviewer:	Sophia Abraham, Ph.D.
Submission Type:	NDA (Supplement)

An OCPB consult is requested for this NDA supplement.

The purpose of this NDA supplement is to update methods validation package, including updated labeling, which was also submitted in the filing of October 11, 2002. The October 11, 2002 filing included a list of NDA samples, regulatory specifications, analytical methods, and methods validation reports utilized to control the quality of carboplatin drug substance and PARAPLATIN® — Injection. PARAPLATIN® — is indicated for the treatment for the initial treatment of advanced ovarian carcinoma in established combination with other approved chemotherapeutic agents

The updated labeling does not contain any change in the Clinical Pharmacology/ Pharmacokinetics, Precautions, and Dosage and Administration sections regarding the use of PARAPLATIN® — Injection.

RECOMMENDATION

No action is indicated.

Team Leader: Atiqur Rahman, Ph.D.
Division of Pharmaceutical Evaluation I

Reviewer: Sophia Abraham, Ph.D.
Division of Pharmaceutical Evaluation I

cc: NDA: 20-452
HFD-150/Division file
HFD-150/Cottrell, Cohen, Dagher, Farrell
HFD-860/Mehta, Sahajwella, Rahman, Abraham
CDR/Biopharm

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sophia Abraham
2/11/03 02:27:13 PM
BIOPHARMACEUTICS

Atiqur Rahman
2/12/03 11:07:14 AM
BIOPHARMACEUTICS